UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A., Plaintiff, v. GLAND PHARMA LIMITED, Defendant.	Civil Action No. 22-4635 (ZNQ)(LHG) [redacted]

CONSENT JUDGMENT AND DISMISSAL ORDER

This action for patent infringement (the "Litigation") has been brought by Plaintiff Helsinn Healthcare S.A. ("Helsinn") against Defendant Gland Pharma Limited ("Gland") for infringement of U.S. Patent Nos. 8,426,450, 8,895,586, 9,186,357, 9,403,772, 9,908,907, 10,208,073, 10,624,911, 10,717,721, 10,828,297, and 11,312,698 (the "Helsinn Patents"). Helsinn's commencement of the Litigation was based on its receipt of notice from Gland that Gland had filed Abbreviated New Drug Application ("ANDA") No. 217374 with the United States Food and Drug Administration ("FDA") containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) directed to the Helsinn Patents and seeking approval to market generic EQ 11.75 mg/mL fosnetupitant chloride hydrochloride and 0.0125 mg/mL palonosetron hydrochloride, 235 mg/0.25 mg per 20 mL single-dose vials for intravenous administration.

Helsinn and Gland have resolved this Litigation on the expectation and belief that this would eliminate the substantial litigation costs that would otherwise be incurred by both Helsinn and Gland during the Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with litigation. This resolution will afford Helsinn and Gland the procompetitive opportunity to more productively use money

and other resources that would have been spent in the continued prosecution and defense of this Litigation, to the benefit of the parties and consumers alike, such as by investing more money in pharmaceutical research and development.

The Court, upon the consent and request of Helsinn and Gland, hereby acknowledges the following Consent Judgment and, upon due consideration, issues the following Dismissal Order.

Helsinn and Gland now consent to this Consent Judgment and Dismissal Order and

IT IS ON THIS 18th DAY OF JANUARY 2023, HEREBY ORDERED, ADJUDGED AND DECREED that:

1. Subject matter jurisdiction, personal jurisdiction, and venue solely with respect to the Litigation are all proper in this Court.

2. In this Litigation, Helsinn has charged Gland with infringement of the Helsinn Patents in connection with Gland's submission of ANDA No. 217374 directed to EQ 11.75 mg/mL fosnetupitant chloride hydrochloride and 0.0125 mg/mL palonosetron hydrochloride, 235 mg/0.25 mg per 20 mL single-dose vials for intravenous administration to the FDA.

3. In response to Helsinn's charges of patent infringement, Gland has alleged certain defenses and counterclaims. No decision has been obtained by the parties from this Court regarding these charges of infringement or these defenses and counterclaims.

4. Gland has not rebutted the statutory presumption that the Helsinn Patents are valid and enforceable in the Litigation. This admission is without prejudice to Gland's defenses and counterclaims that the Helsinn Patents are invalid.

5. Gland admits that the submission of ANDA No. 217374 containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of generic EQ 11.75 mg/mL fosnetupitant chloride hydrochloride and 0.0125 mg/mL palonosetron hydrochloride, 235

mg/0.25 mg per 20 mL single-dose vials for intravenous administration within the United States before the expiration of the Helsinn Patents was a technical act of infringement of the Helsinn Patents under 35 U.S.C. § 271(e)(2)(A).

6. All claims, counterclaims, and affirmative defenses presented by Helsinn as between it and Gland, or by Gland, in the Litigation are hereby dismissed without prejudice.

7. Gland, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them shall not engage in manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic EQ 11.75 mg/mL fosnetupitant chloride hydrochloride and 0.0125 mg/mL palonosetron hydrochloride, 235 mg/0.25 mg per 20 mL single-dose vials for intravenous administration that are the subject of ANDA No. 217374 until [redacted] or at such earlier date as agreed to by the Parties.

8. Helsinn and Gland each expressly waives any right to appeal from this Consent Judgment and Dismissal Order.

9. This court retains jurisdiction over Helsinn and Gland for purposes of enforcing this Consent Judgment and Dismissal Order.

10. The Clerk of the Court is directed to enter this Consent Judgment and Dismissal Order forthwith.

THE HONORABLE ZAHID N. QURAISHI, U.S.D.J.